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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,993	06/27/2001	Kelly R. Brown	ETH-1567	3764
7590	03/10/2004		EXAMINER	
SELITTO, BEHR & KIM 203 MAIN STREET METUCHEN, NJ 08840			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/892,993	BROWN ET AL.
	Examiner Blessing M. Fubara	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4 and 6-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 and 6-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment and corrected drawings filed 11/13/03 and petition filed 12/11/03. Claims 1-4 and 6-28 are pending.

Drawings

1. The corrected formal drawings filed 11/13/03 are acceptable.
2. Applicants' arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 6-17, 23 and 24 rejected under 35 U.S.C. 102(e) as being anticipated by

Vyakarnam et al. (6,333,029)

The applied reference has a common inventor/assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Vyakarnam discloses a composite porous scaffold (column 7, line 6) or structure comprising porous bioabsorbable polymer foam (column 3, lines 65 and 66; column 4, line 39) and materials selected from proteins/peptides, chemotactic agents, therapeutic agents and ceramic materials (column 17, lines 25-53 and claims 1, 21, 42 and 63). Vyakarnam discloses that features of the foam can be controlled by choosing appropriate conditions to form the foam during lyophilization and in so doing the foam can be controlled to suit the desired application (column 4, lines 1-13). The foams of Vyakarnam are composed of polymers selected from aliphatic polyesters, poly(amino acids), copoly(ether-esters), and other polymers listed in column 9, line 31 to column 11 line 13); and aliphatic polyesters include homopolymers and copolymers of lactide or p-dioxanone (1,4-dioxan-2-one, column 9, line 43). Vyakarnam discloses that the foam is formed by lyophilization (column 20, lines 12-61). The polymer of Vyakarnam can be solidified with films, scrims, woven, nonwoven, knitted or braided textile structures, absorbable or non-absorbable or mixtures thereof (column 14, lines 47-56). Vyakarnam also discloses that collagen or elastin or biocompatible ceramic materials and combinations thereof can be used to partially or completely fill the pores (column 17, lines 31-35). Vyakarnam discloses that the gradient scaffold can be used at bone, spine disc, articular cartilage, meniscus, fibrocartilage, tendons, ligaments, dura, skin. Vascular graft, nerves, liver and pancreas (column 5, lines 13-17) and the composite foam structure is used to regenerate or repair osteochondrial defects and cartilage (column 5, lines 57 and 58); cells can invade the scaffold (column 2, lines 57 and 59).

For one set of pores to be larger than another set of pores is relative and the teaching of Vyakarnam meets the limitation. The teachings of Vyakarnam meet the limitations of the claims.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-4 and 6-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. (US 5,084,051) in view of Vyakarnam et al. (US 6,333,029).

Tormala discloses a biocomposite material that comprises at least partially porous bioceramic component and porous material component where the material component comprises resorbable polymer selected from the group consisting of polymer, copolymer, polymer mixture and ceramic materials and mixtures thereof (abstract, column 5, lines 9-64, column 6, lines 12-40 and claims 1 and 2). Specific polymers are polyglycolic acid, polylactic acid and others lists in Table 1 and claim 2 and these polymers are biodegradable. The bioceramic component and the polymer material component are mechanically reinforced with fibers (column 9, lines 1-10).

The bioceramic component is composed of materials selected from calcium phosphate, fluoroapatite, calcium carbonate, magnesium calcium phosphate, bioglasses, glass ceramics or mixtures of ceramics (column 6, lines 41-46 and claim 4). In column 11, lines 2-14, Tormala discloses that the material component penetrates at least somewhat into the pores of the bioceramic during the manufacturing process of the biocomposite. The polymer component can be reinforced with fabric or with parallel or randomly oriented fibers and the reinforcement material can be made of resorbable materials such as polymer, copolymer, polymer mixture and/or ceramic material (column 8, lines 57-67 and column 9, lines 45-52).

Tormala discloses the biocomposite material of the instant claims but fails to specifically state that the composite material comprises polymer foam. Nonetheless, Tormala discloses drying the composite material and the solvent is evaporated under vacuum (column 19, 5, 17 and 27). Regarding claim 8, reinforcement structure could be any polymer disclosed in Tormala. In this regard, it may be noted that Tormala in column 9, lines 45-50 discusses that the reinforcement material can be any of the polymer disclosed in Tables 1 and 2 and also in example 4, PGA/PLLA fiber fabric is the reinforcement material. Thus the PGA/PLLA can be substituted for by any of the other polymers including poly-dioxanone (PDS) with the expectation of achieving the desired reinforcement. Regarding the amounts of each of the polymers in the mixed polymer component, it is within the purview of the person of skill or ordinary skill in the art to use appropriate amounts of each of the polymer in the mixed polymer component with the expectation of providing desired mechanical properties. Vyakarnam discloses that lyophilization produces foam (column 4, lines 2 and 3).

Since lyophilization or freeze drying is an alternate drying process, it would have been obvious to one of ordinary skill in the art at the time the invention was made to dry the biocomposite material of Tormala under normal conditions or under vacuum. One having ordinary skill in the art would have been motivated to freeze dry or lyophilize the biocomposite material of Tormala with the expectation that, substituting lyophilization for drying under vacuum or drying without vacuum would produce a composite that is a foam since lyophilizing produces a foam according to Vyakarnam.

7. Claims 18-22 and 25-28 are rejected under 35 U.S.C. 103(a) as being obvious over Vyakarnam et al. (6,333,029).

The applied reference has a common inventor/assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Vyakarnam discloses the instant scaffold and method of repairing osteochondrial defects and cartilage. Vyakarnam does not teach that the scaffold is placed at the site with the ceramic phase adjacent to the bony tissue. However, there is no demonstration in applicants' specification that placing the scaffold with the ceramic phase adjacent to the bony tissue is critical for the desired effect. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composite of Vyakarnam to repair defect. One having ordinary skill in the art would have been motivated to secure the scaffold of the prior

art at the site of repair in a position or orientation that would produce the desired effect of repairing the defect.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-4, 6-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,626,950. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant composite scaffold encompasses the prosthetic implant of the issued patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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